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Atty. Docket No.: P70821US0

REMARKS

The Office Action mailed June 15, 2007, has been carefully reviewed and, by this Amendment, Applicants have amended claims 1, 7, 11, 12 and 14-17. Claims 1-18 are pending in the application. Claims 1, 7, 12 and 14 are independent. Claim 18 has been withdrawn.

As an initial matter, Applicants have provided replacement drawing sheets herewith in which the reference numerals have been more clearly and fully set forth. Entry thereof is requested.

The Examiner objected to claim 14 as containing informalities which Applicants have corrected herein. Withdrawal of the objection is requested.

The Examiner rejected claims 1-15 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,423,782 to Wolrich in view of DE 19519069 to Brie, and also rejected claims 11 and 15-17 as being unpatentable over Wolrich and Brie and further in view of U.S. Publ. No. 2004/0064132 to Boehringer et al.

Each of independent claims 1, 7, 12 and 14 has been amended herein to more specifically define the structure of the inner bag liner used with an ostomy appliance having a receiving bag in accordance with the present invention. As provided in each

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of these claims, the inner bag liner is folded along a plurality of folding lines so as to be compacted lengthwise prior to use. These folds are provided between the entrance opening and the bottom of the bag liner so that, in the folded compacted condition, *the inner surface of the liner bottom faces and is adjacent the bag liner entrance opening*. With this structural configuration, the initial wastes exiting the stoma, ureter or catheter come into immediate contact with the inner surface of the *liner bottom* so as to force the bottom away from the entrance opening, reducing the risk of pancaking. The inner liner is then gradually unfolded automatically toward the bottom of the receiving member according to the output of the stoma. This claimed structure is supported in the specification on page 9, lines 6-9; page 17, lines 16-18, and in the drawing Figures, and is not shown or suggested by the prior art.

Wolrich teaches the use of a bag liner 38 within an ostomy bag 12. As acknowledged by the Examiner, Wolrich does not teach or suggest that the bag liner 38 is folded along a plurality of folding lines.

Brie discloses a bag for collecting body waste from a colostomy having an inner bag positioned in a conventional two-part colostomy bag. In the initial position, the inner bag is folded

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and, prior to use, the bag may be unfolded by blowing air into the bag (see column 2, lines 2-3 and 12-13 of the German text; page 1, paragraphs 8 and 9 of the English translation text). Based on this disclosure, the Examiner stated that the bag of Wolrich is "necessarily configured to automatically unfold in response to receipt of waste exiting the stoma". Applicants respectfully disagree.

As discussed with the Examiner during a personal interview on August 31, 2007, concerning two other ostomy appliance applications also belonging to the present assignee of this application, the pressures and air flow rates of ostomy bags must be properly balanced to avoid the two extremes of pancaking and ballooning. The fact that waste material has access to the opening of an ostomy bag does not guarantee that the bag will expand to receive it. Rather, under the right conditions the side walls of the bag will adhere to one another, i.e., "pancake", effectively blocking any further waste that is exiting the stoma from entering the bag (see page 17, lines 20-23).

To avoid this pancaking result, Brie teaches that the bag must first be expanded by blowing air into it to ensure it expands. If unfolding of the bag was considered by Brie to be an automatic

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response to the presence of incoming waste as the Examiner suggests, blowing up of the bag first would be unnecessary.

More broadly, neither Wolrich nor Brie is concerned with the problem of pancaking. However, were a person skilled in the art to seek guidance from these references in solving this problem, Wolrich and Brie would not provide a solution.

Wolrich discloses that the inner bag liner is used by inserting the main body portion 40 into the opening 28 in a conventional ostomy bag (see column 8, lines 33-51). It is evident that the inner bag liner of Wolrich is inserted in an unfolded configuration (see Figure 5 of Wolrich). Accordingly, Wolrich does not speak to a folded inner liner structure that will avoid pancaking.

Brie discloses that the inner bag may advantageously be folded in its initial position (see column 2, lines 2-3 and lines 66-67 of the German text; page 1, paragraph 8 and page 2, paragraph 5 of the English translation text), and that, upon blowing of air into the inner bag, the inner bag unfolds into the colostomy bag (column 2, lines 12-13 and lines 67-68 of the German text; page 1, paragraph 8, and page 2, paragraph 5 of the English translation text). Accordingly, Brie clearly teaches that in order to ensure

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the inner bag will be in a configuration to collect waste, the user must actively unfold the bag by blowing air into the bag.

Further, Brie does not teach the skilled person how to fold the bag. Indeed, all that is disclosed is shown in Figure 4, with no supporting discussion thereof in the specification text. Should the skilled person try to derive the necessary teaching from Figure 4, it is evident that the drawing includes two hatched elements which are not connected to each other. It is entirely unclear to one of ordinary skill in the art which parts of the inner bag are represented by the hatched elements and how the two hatched elements are interrelated. At a minimum, there is nothing that would allow one to deduce from Figure 4 that the *inner surface of the bottom of the inner bag* is facing and adjacent the opening to the inner bag, as provided in each of the independent claims as amended herein. And it is this manner of folding the inner bag liner that ensures that waste material initially exiting the stoma will press against the *bottom* of the inner bag, forcing the bag to unfold.

For at least the foregoing reasons, claims 1, 7, 12 and 14 are patentable over the prior art. Claims 2-6, 8-11, 13 and 15-18 are also in condition for allowance as claims properly dependent


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on an allowable base claim and for the subject matter contained therein.

With this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By  No 40,495  
Harvey B. Jacobson, Jr.  
Reg. No. 20,851

400 Seventh Street, N.W.  
Washington, D.C. 20004-2201  
Telephone: (202) 638-6666  
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